MAIL ROOM MAY 20 1997 PAT. & TRADEMARK OFF.

Attach #10

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent appln. of:	CARL F. KNOPP, et al	Group Art Unit: 2515
Serial No.:	08/404,253	Examiner: H. MAI
Filed:	March 15, 1995	
For:	APPARATUS AND METHOD FOR IMAGING ANTERIOR STRUCTURES OF THE EYE	
Docket No.:	356-94	

AFFIDAVIT UNDER 37 CFR 1.131

RECEIVED ... 1997 GROUP 2500

Honorable Commissioner of
Patents & Trademarks
Washington, D.C. 20231
Sir:

State of California)
) S.S.
County of Alameda)

I, Carl F. Knopp, being duly sworn, depose and state:

1. I am the inventor of claims 6, 21, 22, 29 and 50 of the above-identified patent application.

2. Prior to October 26, 1994, I had completed my invention as described and claimed in the subject application in this country or a NAFTA country, as evidenced by the following:

a. Prior to October 26, 1994, I conceived the idea of a slit lamp assembly having means for projecting convex slit images comprising a curved slit as described and claimed in my application. An engineering drawing of an embodiment of the invention was prepared by me prior to October 26, 1994, a copy of which is attached hereto as "Exhibit A".

b. Prior to October 26, 1994, I reduced to practice the invention by making a model of the invention shown in Exhibit A and by conducting a series of tests. My reduction to practice of the invention was witnessed by Mr. Jan Wysopal. Mr. Wysopal assisted me in making of the model of the invention shown in Exhibit A as well as the testing of

5/14/97 Carl F. Knopp

5/14/97 Carl F. Knopp

that model. The test results using the model according to Exhibit A were compared against a similar slit lamp assembly but with a planar slit which projected planar slit images. In each of the test trials, light from the slit lamp assembly was projected onto the cornea and then a picture of the cornea was taken. The test results showed a decided improvement in the definition of the corneal pictures when using the slit lamp assembly according to Exhibit A than when using the slit lamp assembly having the planar slit. An affidavit of Mr. Wysopal is enclosed as "Exhibit B" corroborating my reduction to practice of the invention as shown in Exhibit A. Also enclosed as "Exhibits C_1 and C_2" are two pages of notes taken from my records stored on a hard drive, which is additional evidence of my reduction to practice of the invention shown in Exhibit A. On Exhibit C_1, the third line up from the bottom of the page, the entry reading "Test curved slit" and on Exhibit C_2, six lines from the top of the page, the entry reading "Curved slit works much better than straight one - have sharp definition of cornea everywhere - we should use the curved one" both were made prior to October 26, 1994.

5/14/97
Carl F Knopp

c. Prior to October 26, 1994, I prepared a written description of the invention (copy attached as "Exhibit D") which was also sent prior to October 26, 1994 to my patent attorney, Mr. McConnon by facsimile.

2. Each of dates deleted from Exhibits A, C_1, C_2 and D are prior to October 26, 1994.

Date: 5/14/97

Carl F Knopp
Carl F. Knopp

Sworn to and subscribed before me this 14th day of May, 1997.

Joseph Ramirez
NOTARY PUBLIC

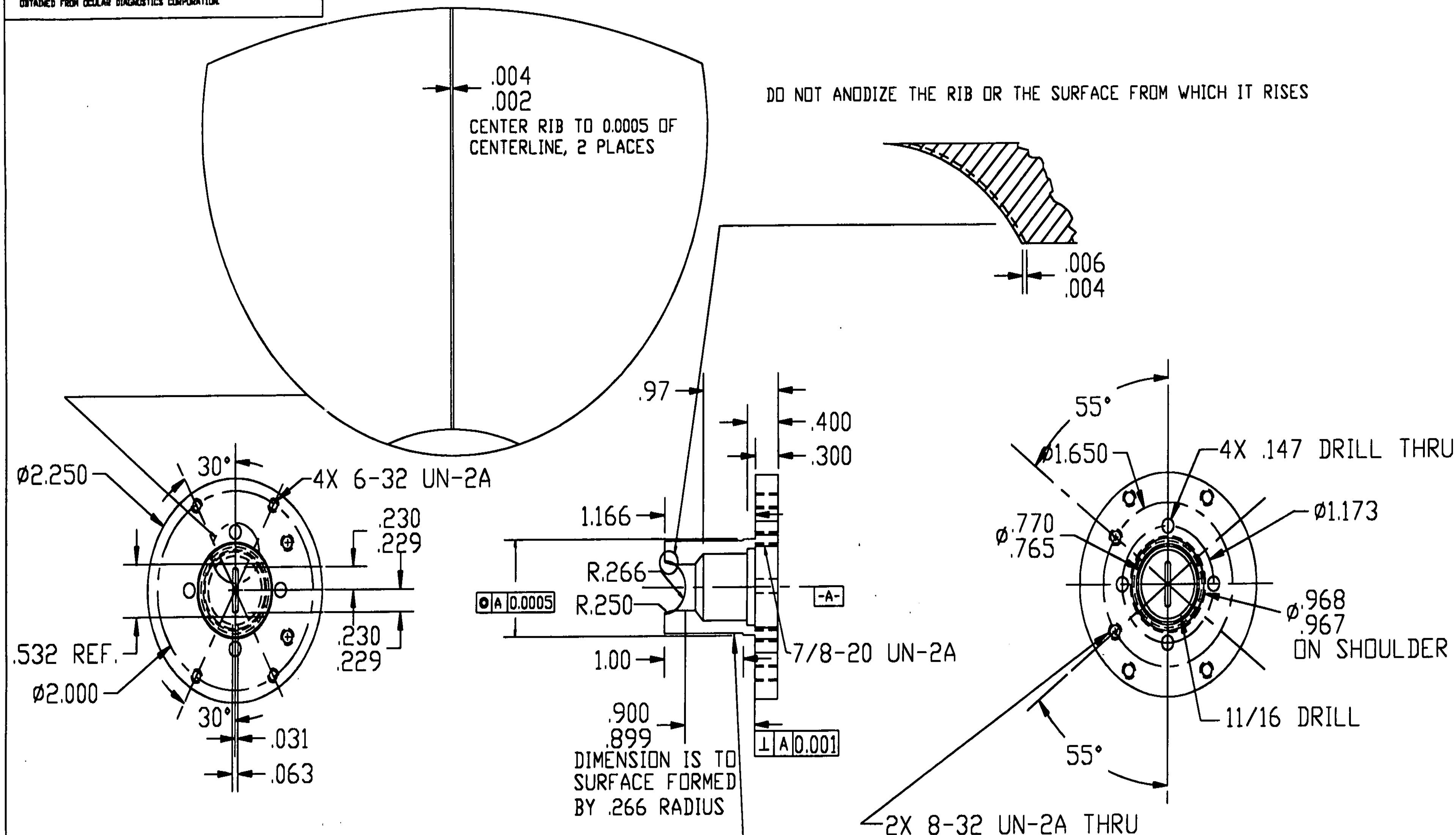
JOSEPH RAMIREZ
Commission #1088130
Notary Public — California
Alameda County
My Comm. Expires Feb 19,2000

EXHIBIT

A

PROPRIETARY NOTICE

		QTY	PART NO.	UNIT/M	DESCRIPTION	ITEM #



NOTE: .063 SLOT CENTERED TO .001 OF -A-

DASH #	NEXT ASSY	REV	DATE	ECO #	INC BY	CHECK	DESCRIPTION OF REVISIONS
-	0001-1000	5		-	CFK		PRE-RELEASE

DO NOT SCALE DRAWING

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

TOLERANCES:
.X = ± .1
.XX = ± .01
.XXX = ± .005

ANGLES: 30'
FINISH: 32

BREAK AND DEBURR SHARP EDGES

CONDENSOR HOUSING, CURVED

SCALE	DRAWN BY	DATE	CHECKED BY	APPROVAL
1/1	CFK			

MAT'L: ALUMINUM, 6061-T6

FINISH: BLACK ANODIZE, EXCEPT AS NOTED

OCULAR DIAGNOSTICS CORPORATION

48041 FREMONT BLVD. 94538

B 0001-0050 SHEET 1 OF 1 REV 5

EXHIBIT

B

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent appln. of:	CARL F. KNOPP, et al	Group Art Unit: 2515
Serial No.:	08/404,253	Examiner: H. MAI
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For:	APPARATUS AND METHOD FOR IMAGING ANTERIOR STRUCTURES OF THE EYE	
Docket No.:	356-94	

DECLARATION OF JAN ~~WISOPAL~~ Y JW 5/14/97

Honorable Commissioner of
Patents & Trademarks
Washington, D.C. 20231

Sir:

State of California)
) S.S.
County of ALAMEDA)

JW 5/14/97

I, Jan W~~i~~Ysopal, being duly sworn, depose and state:

1. Prior to October 26, 1994, I assisted Mr. Carl F. Knopp in making a model of a slit lamp assembly having a curved slit to project convex slit images. The model was based on an engineering drawing prepared by Mr. Knopp, which is enclosed as "Exhibit A". Under Mr. Knopp's direction, a series of tests were performed with the model of the slit lamp assembly having the curved slit and the tests were compared against test results using a model of a similar slit lamp assembly but having a planar slit. In each of the test trials, the light from the slit lamp assembly was projected onto the cornea and then a picture of the cornea was taken. The test results show that there was a decided improvement in the definition of the corneal pictures when using the slit lamp assembly having the curved slit than when using the slit lamp assembly having the planar slit. Each of these experiments were completed prior to October 26, 1994.

2. Each of the dates deleted from Exhibit A is prior to October 26, 1994.

3. I am aware that willful false statements and the like herein are punishable by fine or imprisonment, or both (18 USC 1001) and may jeopardize the validity of the patent application or any patent issuing based thereon.

4. All statements made of my own knowledge herein are true, and all statements made herein on information and belief are believed to be true.

Date: 5/14/1997

Jan Wysopal
JW 5/14/97

Sworn to and subscribed before me
this 14th day of May, 1997.

NOTARY PUBLIC

JOSEPH RAMIREZ
Commission #1088130
Notary Public — California
Alameda County
My Comm. Expires Feb 19,2000

EXHIBIT

C1

Tasks for ODC

Incorporation completed

Get comparison data on competitors ....

Generate projected financial data ....

Develop business plan ....

Funding contacts started

Distribute initial 25 business plans ....

Finish detailing of prototype design ....

Release rest of prototype design ....

Design a curved slit ....

Assemble prototype ....

Adapt motor controller software ....

First tests of prototype ....

Test curved slit ....

Head rest - design or build?

Lateral motion of optics or patient?

Tasks for ODC

Business plan is completed

11 Business plans sent out

Contact Chiron, Alcon, EyeSys ....

Get passes for AAO ....

Curved slit works much better than straight one - have sharp definition of cornea everywhere - we should use the curved one

Develop a least squares spherical curve fit for data ....

Demo here for AAO...

Motor is heating up too much - change to Compumotor.............................

DEVICE FOR OBTAINING THE SHAPE AND GEOMETRICAL DIMENSIONS OF THE CORNEA IN THREE DIMENSIONAL SPACE

BACKGROUND OF THE INVENTION

The present invention relates to a device for measuring the cornea of an eye in three dimensions by employing computer assisted visual tomography. The device provides coordinates for both the anterior and posterior surfaces ~~as~~ well ~~as the~~ distance between them. From these data an accurate reconstruction of the cornea and description of its optical power can be made.

Instruments to measure the topography of the anterior surface of the cornea with the aid of a computer and an "expert" program are widely available and have been used for several years. These instruments rely upon examining the reflection of a light pattern projected onto the cornea. This technique is known to produce data of questionable accuracy and over a limited portion of the cornea, as described in the journals *Investigative Ophthalmology and Visual Science*, Volume 35, 1994, pages 3525-3532, and *Refractive & Corneal Surgery*, Volume 9, pages 347-357.

A second technique that might be applied to the measurement of corneal curvature and thickness has been described in U.S. Pat. No. 4,171,877 and 4,523,821. Both of these instruments have the disadvantage in that they employ the use of slit illumination in conjunction with the Scheimpflug principle. This principle causes the instrument using it to become optically and mechanically complex and expensive. Neither of these two patents made any claims as to the ability to measure completely the cornea and construct a three dimensional accurate representation of it.

BRIEF STATEMENT OF THE INVENTION

The object of the invention is to provide an instrument by which direct measurements can be carried out on the cornea of the eye in order to determine the geometrical shape in three dimensions. To this end the anterior and posterior curves of the cornea, the distance between these two surfaces, and the distance of the lens posterior to the cornea are to be measured. This is to be accomplished in a simple instrument without the complexity and expense of employing the Scheimpflug principle. The instrument provides a method for accurately and reproducibly establishing a reference axis which is coincident with the patient's line of sight (sometimes called the visual axis), so that all measurements which are taken are centered about the line of sight. This provides the best possible reference point for taking measurements of the anterior portion of the eye, as described in XXXXXXX. to be furnis[h]

The invention achieves this object by imaging a narrow slit of electromagnetic radiation, preferably in the far red to near infrared portion of the spectrum, upon the cornea. The narrow slit or "slice" of illumination has a length such that it reaches across the entire diameter of the cornea and a width that is very narrow compared to the positional accuracy with which the data is to be acquired. The illumination passes through the cornea, a small portion of it being reflected from the anterior surface of the cornea, an even smaller portion from the posterior surface of the cornea, and some being scattered from within the interior structure of the cornea. If visible radiation is used it is clearly visible to the naked eye, a phenomenon long employed in the slit lamp examination instruments of ophthalmologists.

The slice of radiation is rotated about the patient's line of sight. Also rotated about the line of sight, and generally physically attached to the slit from which the radiation emanates, is a data acquisition system consisting of video camera and lens system which lies at an angle of approximately 45 degrees to line of sight of the patient while data is being acquired. The data acquisition system is oriented so that it is perpendicular the cross section of the cornea illuminated by the slice of radiation and is focused upon it. As the camera and illumination are rotated, the visual axis of the patient

always lies within the plane defined by the optical axis along which the slit is projected and the optical axis along which the data acquisition system views the cornea. This is caused by the patient viewing a fixation system which consists of two fiducials, one located optically at infinity and the other located optically approximately one meter away from the patient. The fiducial located at infinity appears to remain fixed in space regardless of the angle that is viewed through the optics of the invention. The nearer fiducial appears to the patient to move very quickly as the patient's eye deviates from being colinear with the optical axis of the instrument. While the patient maintains the alignment of these fiducials the coincidence of the optical axis of the instrument and the visual axis of the patient's eye will be in a known and repeatable orientation with respect to the to the data that is acquired.

The data is taken by positioning the data acquisition and slice of illumination at a desired point, capturing and storing the electronic image into computer memory, then moving to the next position, until examination of the area under interest has been completed. Once all of the captured electronic images have been acquired, which normally involves the rotation of the slice of illumination by 180 degrees, they can accurately be referenced to one another because each has a common reference point, the intersection of the axes of the optical axis along which the patient is looking and the axis along which the data were acquired.

Prior to this invention the establishment of a reference point for measurements of the eye has been restricted to noting physical features of the eye such as the pupil, or reflex images from the eye, such as the various Purkinje images as taught in U.S. Pat. No. 4,523,821. The alignment method taught in U.S. Pat. No. 5,110,200 can be seen to rely upon a single fixation point for the patient. It will be appreciated that a single point does not establish a unique line, such as is needed to establish the line of sight. All of the methods used prior to this invention have the same drawback: there is no ability to reference the data taken to the patient's line of sight and no certainty that the position of the eye with respect to the instrument can be repeated in a subsequent measurement.

It is possible and even likely that the patient will experience involuntary eye motion during the time necessary to acquire the necessary electronic images. This time can be as long as 15 seconds. If the view of the patient were to deviate from the optical axis of the instrument the construction of the corneal image from the acquired data would be in error due to the lack of a common reference point for all of the images. Small involuntary movements of the eye have not generally been found to cause significant error in constructing the three dimensional corneal map but a means for eliminating this potential error has been incorporated into the invention. It consists of a second camera, synchronized with the camera of the data acquisition system, which captures an electronic image of the eye from directly along the patient's line of sight. This image, when used in conjunction with the image from the data acquisition camera, provides a measurement in three dimensional space of the deviation, if any, of the patient's line of sight at the moment that the electronic pictures were taken. With this information it is possible to correct the reference point on any electronic image to bring it into coincidence with the point defined when the first image was acquired.

DETAILED DESCRIPTION

An illustrative embodiment of the invention will be described in conjunction with the accompanying drawing, in which:

FIG 1 is a diagram showing construction of the optical and mechanical portion of an instrument of the invention;

FIG 2 is a block diagram of the major system components of the instrument;

FIG 3 is a block diagram to show processing of the data produced by the portion of the instrument shown in FIG 1;

FIG 4 illustrates the manner in which proper focus of the instrument of FIG 1 with respect to the cornea of the eye is obtained; and

FIG 5 depicts a typical data presentation provided to the user.

In the optical system of FIG. 1, the slit 4 is illuminated by the lamp 2. The condenser lens 3 is chosen so that the slit is completely illuminated and the lamp filament 1 is imaged into approximately the principal plane of the projection lens 7 so as to fill projection lens 7 in the direction along the long portion of the slit. The focal length of the condenser lens is about 17-mm. The projection lens 7 projects illumination from the slit 4 along the optical axis 21 of the instrument. The slit 4 is formed as a portion of a cylinder, the long axis of the slit lying upon the circumference of the cylinder. It is concave toward the projection lens 7. The purpose of this is to create a focal plane for the slit image which is curved in the opposite direction from that which would normally be formed with a planar slit, so that the image of the slit is brought to focus across substantially the entire surface of the cornea upon which the illumination falls. The slit is about 0.2 to 0.3-mm in width and has a dimension along its chord of about 13-mm. The slit 4 is mounted coaxial with rotor 17 and affixed to it.

Located between the projection lens 7 and the slit 4 is a mirror 6 which has the property of transmitting radiant energy in the red to near infrared region of the electromagnetic spectrum, and reflecting energy in the visible portion of the spectrum. The purpose of the mirror 6 is to provide an optical path for the patient to view the alignment assembly consisting of two fixation targets 8 and 8A, lens 22 and illumination filament 23, while permitting the illumination from slit 4 to pass through lens 7 and be focused on the cornea C.

A compensating plate 5 is located between the slit 4 and mirror 6. The purpose of the compensating plate 5 is to correct astigmatic aberrations in the image of the slit which would be produced by the non-parallel illumination between the projection lens 7 and the slit 4 if it were to pass through a single parallel plate lying at an angle to the illumination. This correction would not be necessary if the illumination were made parallel by placing an additional lens between the mirror 6 and the slit 4 focusing the slit at infinity and re-focusing the parallel illumination with the projection lens 4, however this results in a more expensive and complex instrument.

The bulb 2 is chosen with a rectangular filament and is affixed to rotor 17 through an electrically insulated mounting so that the filament 1 is parallel to slit 4. In FIG. 1, slit 4 and filament 1 are shown rotated 90 degrees out of the plane of the paper for clarity. In the embodiment of the invention they are both oriented to be perpendicular to the plane defined by the optical axis 21 and the viewing axis 24.

The image capture assembly 13 consists of the filter 25, the lens 14 and the camera 15 which have the mutual viewing axis 24. The assembly is oriented at about 45 degrees to the optical axis 21 and focused at the point C where these two axes intersect. The image of the slit on the cornea C produced by the projection lens 4 makes visible a cross section of the cornea which is formed by the reflection of light from the corneal surfaces and the scatter of light from between these surfaces. This light, which has been restricted to the red and infrared portion of the spectrum by mirror 6, is imaged upon the camera by lens 14 after passing through filter 25. Filter 25 is a long pass filter which permits only deep red and near infrared light to be transmitted. Its purpose is two fold. The first is to reject visible illumination that falls upon the cornea from the illumination source 23 of the fixation assembly 26. The second purpose is to reject ambient light, particularly that from fluorescent lighting. In the preferred embodiment lens 14 is actually an anamorphic lens assembly which produces an image that

is magnified more greatly across the cross section of the cornea than along its length, generally having a ratio of magnification of about 4. In the preferred embodiment the camera **15** has a ccd array with 512 x 512 pixel resolution or greater and that has its maximum sensitivity in the red and near infrared region of the electromagnetic spectrum.

The rotor **17** has the lamp **2**, the condenser **3**, the slit **4** and the image capture assembly **13** affixed to it in the orientation described above. The rotor **17** is free to turn in the two bearings **10** and **11** and can be driven by the motor **12** through a substantial portion of a complete circle, typically exceeding 310 degrees. Rotor **17** is gripped between the outer race of bearing **11** and the inner race of bearing **10** by means of bearing retainers **19** and **20** respectively. In addition to removing any axial motion of the rotor during operation, these bearing retainers are used during construction to move the rotor and all attached pieces along the optical axis **21** so as to position the slit **4** (and all other pieces attached to the rotor) at the proper distance from the projection lens **7**. This is necessary because of the tolerance limits on the focal length of projection lens **7** which are necessary in order that the lens be manufactured as inexpensively as possible.

The projection lens **7**, the mirror **6**, the compensating plate **5** and the fixation assembly **26** are mounted to holder **16** which passes through the inner race of bearing **10** and is mounted to base plate **27**. The outer race of bearing **11** is contained within housing **18** which is attached to base plate **27**, as is motor **12**. Thus, the slit **4**, condenser lens **3**, lamp **2**, and image capture assembly **13** rotate about the optical axis **21** while all other elements of the invention remain fixed to the base plate **27**.

The motor **12** is typically a stepper motor and is sent signals from the motor controller **2** of FIG. **2** to place the rotor **17** and all attached parts to any desired angular position with respect to an established reference point. However, a motor employing direct current and position sensing or alternating current and a clutch mechanism can be used to accomplish the positioning.

Base plate **27** may be moved to bring the entire instrument closer to or further from the eye. It is constrained to move only in the direction of the optical axis **21** and is used to establish the proper distance of the instrument from the cornea C such that the image of the slit is in best focus. The position of best focus of the slit image is established at the time that the instrument is constructed. This is done by establishing a target, which may be either cylindrical with a radius approximating that of the cornea or flat, at the position of best focus of the image of the slit which projected by the projection lens **4** in FIG. 1. The position of best focus is ascertained by examining the image of the slit upon the target by means of the image capture system which is operated in real time. The target has a fiduciary upon which the image of the illuminated slit is centered. The central pixel of the slit image is found through data acquisition methods similar to that used to find the edge of the images of the corneal cross section. The horizontal location of the central pixel is stored in the instrument's table of global constants as a reference pixel, so that it may be used to create a vertical fiduciary line on the monitor **2** of FIG. 2 which will define the proper position of the patient with respect to the instrument.

During establishment of the proper distance of the instrument from the patient, the vertical fiduciary line is first displayed by the operator upon monitor **2** in FIG 2, using either the mouse **4** or the keyboard **5** of FIG. 2. This vertical line passes through the reference pixel. A real time image of the cross section of the cornea is displayed upon the monitor by the image capture assembly **13**. The instrument is then moved along its optical axis **21** of FIG 1 by moving the base plate **27**. The operator can cause the instrument to be placed in proper focus upon the cornea by observing the real time image of the cross section of the cornea and moving the base plate **27** until the vertex of the image of the cross section is tangent to the vertical fiduciary line.

Fig. 2 shows the principal components of the invention. The patient head rest 31 is very similar to the head rests used in many ophthalmic examination instruments, with the exception that lateral movement, in the direction across the patient's eyes, is provided in addition to the vertical motion usually provided in these devices. The purpose of this additional motion is to provide the patient with a mechanism to place either of their eyes, unassisted by the operator of the device, so that the eye being examined is looking along the optical axis 21 of the optical head 32.

To use the instrument the patient places their head into head rest 31 of FIG. 2 with their forehead against headband 38 and looks toward the optical head 32, which is shown in detail in FIG. 1. The patient move the head rest by use of the vertical adjustment screw 37 and horizontal adjustment 36 slide until the two fiducials 8 and 8A of the alignment assembly 26 of FIG. 1 appear to be centered upon each other. During the time this is occurring, the operator is adjusting the distance between the optical head 32 and the patient P in the manner described above. When the patient informs the operator that alignment is achieved, the operator verifies the correct position along the optical axis 21 and starts the process of data acquisition by initiating a menu selection from the Windows® menu shown on the monitor 33. If this is a routine examination of the complete cornea the software in the computer 34 will cause the motor 12, shown in FIG. 1, of the optical head 32 to move the rotor 17 of FIG. 1, and its attached components, to the initial position and capture and store in computer memory 34 the first image of the corneal cross section. The controlling software then causes the motor to move the rotor 17 of FIG 1, and its attached components, to the next position specified by the software, where it is stopped and the image of the cross section of the cornea at this new angle is recorded and stored in computer memory. This procedure is repeated until the slit image has been rotated 180 degrees from its initial point, giving complete coverage of the cornea. These data are then combined by use of a data construction algorithm into a three dimensional map of the cornea which may be displayed in several different manners upon the monitor 35, stored in computer memory, or saved as a hard copy by use of color printer 36.

The resolution of the corneal map is no better than the number of positions at which the data were acquired. The angular spacing between the positions of data acquisition may be chosen to be of any magnitude. Typically, an angular spacing of 15 degrees is used for a routine examination of the entire cornea. It will be appreciated that a much smaller angular separation over a restricted portion of the cornea has the effect of greatly increasing the resolution of the data acquired that can be employed to form the representation of the cornea. This in effect permits "zooming in" to examine aberrations such as keratoconus in great detail. Because of the nature of the radial scan of the optical probe the tomographic image has the best resolution around the line of sight, exactly where is most important to have the most accurate measurements.

EXAMINER'S AMENDMENT:

please amend Fig. 1 as indicated in red ink.

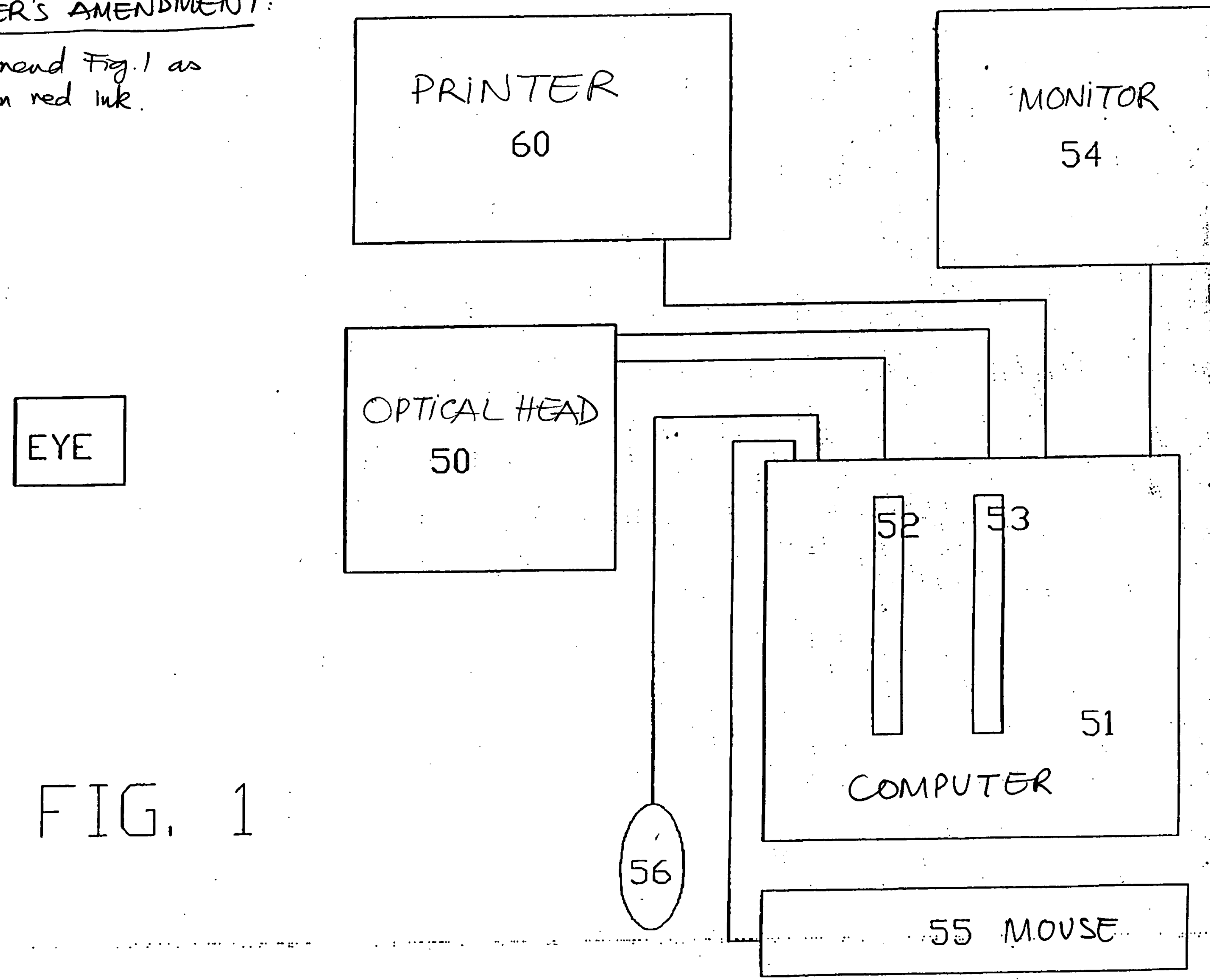

FIG. 1